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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/188,051	11/06/98	SHIRLEY B	5784-25

000826
ALSTON AND BIRD
P O DRAWER 34009
CHARLOTTE NC 28234-4009

HM12/0309

EXAMINER	
MOEZIE,F	
ART UNIT	**PAPER NUMBER**
1654	4
DATE MAILED:	03/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Co

Office Action Summary	Application No. 09/188,051	Applicant(s) Shirley et al
	Examiner Fatemeh Moezie	Group Art Unit 1654

☒ Responsive to communication(s) filed on *Nov 6, 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for IGF-I and arginine, does not reasonably provide enablement for IGF-I or arginine analogues. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The term "analogues" is too broad and an skilled artisan would not be able to make and use all of the analogues as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "analogue" render the claims indefinite as to what is being claimed in the claims. ✓

Deletion of the term from the claims is suggested.

Claims 5, 6, 8, 9, 11, 12 are improper dependent claims, because in fact they depend from or further limit claims 4, 5, 7, 8, 10, 11, respectively. ✓

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al USP No. 5,126,324 and The Merck Index as applied to claims 1-20 above, and further in view of Chang et al USP No. 5,410,026.

The primary reference teaches a pharmaceutical composition comprising IGF-I and a solubilizing compound, eg, a poloxamer. Although, the solubilizer is used to enhance the solubility of GH, it is apparent that it would do the same for IGF-I, because it is considered a pharmaceutic aid according to The Merck Index.

However, the above reference does not teach the use of a compound containing a guanidinium group as the solubilizing agent.

The secondary reference teaches the use of a chaotropic agent render "the IGF-I up to about 90% soluble in the aqueous medium" col.8, lines 21-40; and col. 10, lines 10-41.

One of ordinary skill in the art at the time the invention was made would have expected that the use of a compound having a guanidinium group would enhance the solubility of the resulting composition.

Any inquiry concerning this communication should be directed to Examiner Moezie at telephone number (703) 4508.

F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
ART UNIT ~~186~~ 1654